Efficacy of Directly Observed Treatment in a Residential Health Care Facility for AIDS Patients: A Retrospective Review of 87 Patients

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Introduction:

Since the advent of highly active antiretroviral therapy (HAART), it has been accepted that treatment failure is primarily related to resistant virus and/or poor adherence. To achieve virologic success, HIV-positive patients need to take at least 95% of their prescribed antiviral treatment.(1) Many patients, especially those who are cognitively impaired, mentally ill, or abusing drugs or alcohol, are very poorly adherent to therapy, resulting in virologic and immunologic failure and disease progression.

In 1990, New York State established an enhanced Medicaid reimbursement system to encourage the development of long-term care (LTC) facilities for the specialized treatment of patients with advanced HIV disease. Casa Promesa, located in the South Bronx of New York, was licensed under the New York State Guidelines as a 108-bed LTC facility for AIDS patients. All admissions must have CDC-defined AIDS or symptomatic HIV disease requiring skilled nursing care. At the time of their admission to Casa Promesa, many residents have been precariously housed, living in shelters or SROs, and are actively using drugs, mentally ill, and cognitively impaired. Many have been disengaged from medical care and have not taken their treatment consistently, if at all.

At the time of admission, each resident is assigned to one of four full-time medical providers, all of whom are qualified as HIV specialists according to New York State guidelines. The formulary includes all FDA-approved antiretrovirals and selection of treatment regimens is at the discretion of the individual medical providers. All medications are administered as directly observed treatment (DOT) by the nursing staff, resulting in maximal adherence. This report summarizes the demographics of the resident population, the results of HAART given DOT, and the impact of different ART regimens on treatment success.

Methods:

A retrospective chart audit of all the residents in the facility from March 17-31, 2005 was performed. Residents had to be on treatment for at least 6 weeks to be included in the study. The following indicators were collected: age, gender, racial-ethnic background, HIV risk factors, length of facility stay (LOS), medical comorbidities, substance use history (drug and alcohol), psychiatric diagnoses and treatments, and AIDS-defining illnesses. Because of the large number of different reverse transcriptase inhibitor (RTI) medication combinations used, specific RTI treatment backbones were not identified. Antiretroviral treatments were categorized as reverse transcriptase inhibitor (RTI) based, nonnucleoside reverse transcriptase inhibitor (NRTI) based, or protease inhibitor (PI) based (including single PI, dual PI, and ritonavir-boosted PI).

Results of CD4 cell counts and HIV viral loads (VLs) obtained at the time of admission were used as the baseline values. These were compared to the results of CD4 cell counts and VLs obtained at the time of the audit. CD4 cell counts and VLs were monitored every 3 months in stable residents or repeated within 2-8 weeks of starting or changing treatment. All laboratory tests were done at the facility's usual clinical lab.

Results:

The charts of 111 residents were reviewed. Twenty-four records were excluded from further analysis (14 residents were not on treatment for 6 weeks, 7 residents refused ART, 2 residents had ART discontinued due to hepatotoxicity, and ART was not indicated in 1 resident). The records of 87 residents comprise the final analysis.

Most of the residents are ethnic minorities with 55% Latino and 39% African American. Gender breakdown is male = 75%, female = 23%, and transgendered = 2%. (Table 1)

Table 1: Demographics:

Baseline Characteristics	
Median Age: 47	Transmission Risk Factors
Range: 23-76	IDU: 51%
Gender:	Heterosexual: 38%
Male: 75%	MSM: 7%
Female: 23%	IDU/Sex: 4%
Transgendered: 2%	Length of Stay
Ethnic Breakdown:	Range: 1.5-106 months
African American: 39%	Mean: 23.9 months
Latino: 55%	Median: 14 months
Non Latino White: 6%	

Medical comorbidities included hepatitis C infection = 48%, use of psychotropics = 40%, history of PCP = 17%, CVA with hemiparesis = 13%, dementia = 13%, diabetes = 11%, treatment for active tuberculosis = 10%, and carrier for hepatitis B = 7%. Substance use was a significant problem in the population with 91% relating a history of chemical or alcohol dependence. Most residents abused more than one substance, with 34% using two drugs and 25% abusing three or more drugs. The most commonly used drugs were alcohol (11%), cocaine (9%), heroin (7%), and crack (6%).

Viral loads at baseline ranged from <50 copies/mL (4 residents) to >750000 copies/mL (5 residents). Fifty percent of residents were >100000 copies/mL. The mean baseline VL was 209938 copies/mL with a median VL of 95000 copies/mL. Viral loads after treatment ranged from <50 copies/mL to 37000 copies/mL with a mean VL of 1339 copies/mL and a median VL of 125 copies/mL. Twenty-seven residents (31%) had VLs <50 copies/mL and 64 residents (74%) had VLs <400 copies/mL (Figure 1). Eleven residents with a LOS of <6 months had baseline VLs greater than 100000 (mean VL = 263973 copies/mL). After treatment, their mean VL was 685 copies/mL with 2 of 11 having <50 copies/mL and 9/11 having VLs <400 copies/mL.

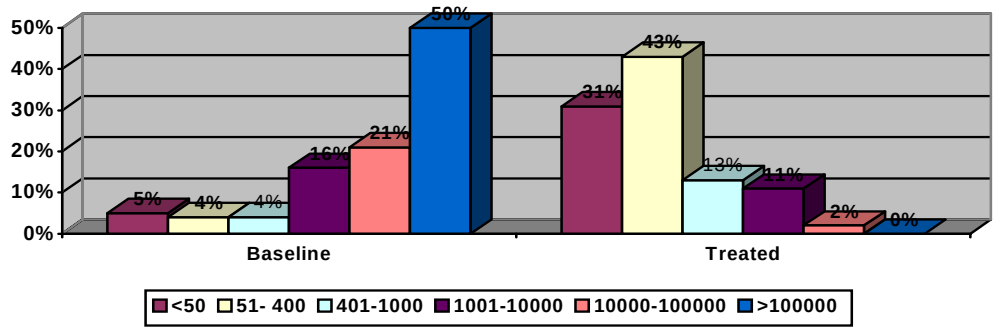

Figure 1: Comparison of Viral Loads at Baseline and after Treatment
Baseline CD4 cell counts ranged from 0-540 cells/µL with a mean of 133 cells/µL and a median of 87 cells/µL. After treatment, CD4 cell counts ranged from 28-1058 cells/µL with a mean of 341 cells/µL and a median of 340 cells/µL. (Figure 2)

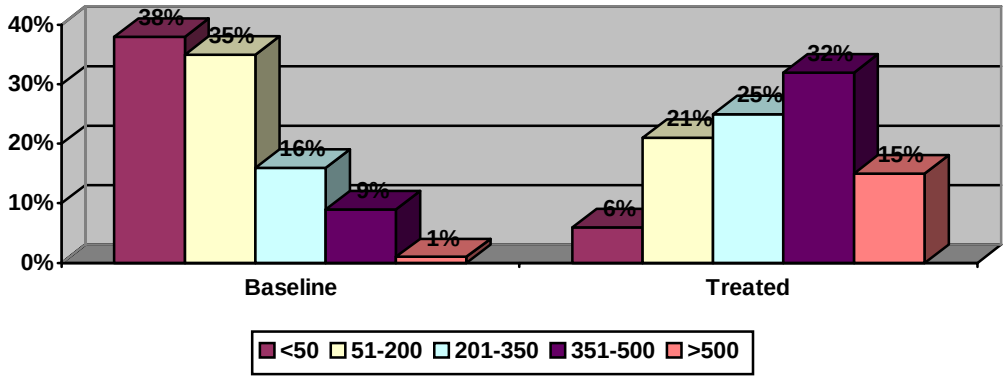

Figure 2: Comparison of CD4 Cell Counts at Baseline and After Treatment

The 87 residents were treated with a variety of treatment regimens. All residents were taking at least three different antiviral medications. Antiviral regimens were categorized as RTI based,(8) NRTI based,(18) single PI,(13) and ritonavir boosted or other PI combinations.(48) Of the 27 residents with a VL <50, treatment regimens were based on nelfinavir,(6) ritonavir-boosted atazanavir,(6) efavirenz,(5) and 6 different regimens (Table 2).(10) Specific RTI treatment backbones were not identified because of the number of different combinations used.

Table 2: Antiretroviral Treatment Regimens

Regimens of 87 Residents			
Regimen	# Residents	Regimen	# Residents
Atazanavir-Saquinavir	1	Triple RTIs	3
Atazanavir-Saquinavir-Enfuvirtide	1	Triple RTIs-Enfuvirtide	1
Atazanavir/ritonavir	13	Quad RTIs	4
Lopinavir/ritonavir-Enfuvirtide	1	Nelfinavir	12
Lopinavir/ritonavir-Saquinavir	4	Nelfinavir-Efavirenz	1
Lopinavir/ritonavir-Atazanavir	1	Efavirenz	13
Lopinavir/ritonavir	19	Nevirapine	5
Lopinavir/r-Efavirenz	1	Saquinavir/ritonavir	1
Lopinavir/ritonavir-Delavirdine	1	Fosamprenavir/ritonavir	5
Regimens of 27 Residents with VL <50 copies/mL			
Nelfinavir	6	Lopinavir/ritonavir	2
Atazanavir/ritonavir	6	Nevirapine	2
Efavirenz	5	Lopinavir/ritonavir-Saquinavir	1
3 RTIs	2	Lopinavir/ritonavir-Efavirenz	1
4 RTIs	2		

Discussion:

These results confirm the efficacy of DOT in a patient population with advanced HIV disease and multiple comorbidities often associated with poor adherence and/or response to antivirals. Similar

benefits of DOT have been reported by others.(2,3,4,5) Genotypic resistance is rarely seen in the residents upon entry to the facility, suggesting that they have not been taking their ART, even when it has been prescribed in the outpatient setting.(6) With the lack of resistance and DOT insuring maximal adherence, it is not surprising that many different treatment regimens were able to effectively decrease viral loads and improve CD4 cell counts.

In Paterson's study on adherence, patients averaged taking 17 pills every day, dosed 2 to 3 times a day.(1) Such complex regimens did not lend themselves well to cost-effective DOT programs. With the development of effective once-daily regimens requiring much lower pill burdens, DOT should be feasible in many more situations. Those patients who have been hardest to engage in care, such as the mentally ill and substance users, may very well require incentives to participate in such programs. It is the challenge for health care planners to design cost-effective DOT programs that can reach these patients and be applied to ambulatory care settings.

Conclusions:

In a group of patients with advanced HIV disease and prior poor adherence to treatment, many different regimens administered DOT effectively worked to decrease viral loads and improve CD4 cell counts. With the simplification of treatment regimens, it is the responsibility for health care planners to design systems that will be able to cost-effectively deliver antiretroviral therapy as directly observed treatment in ambulatory care settings.

References:

1. Paterson DL, Swindells S, Mohr J, et al. Adherence to Protease Inhibitor Therapy and Outcomes in Patients with HIV Infection. Ann Intern Med. 2000; 133:21-30.
2. Fischl M, Castro J, Monroig R, et al. Impact of Directly Observed Therapy on Long Term Outcomes in HIV Clinical Trials. Abstract 528, 8th Conference on Retrovirus and Opportunistic Infections. February, 2001. Downloaded from http://www.retroconference.org/2001/Abstracts/Abstracts/Abstracts/528.htm
3. Conway B, Prasad J, Smith N and deVlaming S. Nevirapine (NVP) and Protease Inhibitor (PI)-Based Regimens in a Directly Observed Therapy (DOT) Program for Intravenous Drug Users (IDUs). Abstract 545-T, 9th Conference on Retrovirus and Opportunistic Infections. February, 2002. Downloaded from http://www.retroconference.org/2002/Abstract/13231.htm
4. Kirkland LR, Fischl M, Tashima KT, et al. Response to Lamivudine-Zidovudine plus Abacavir Twice Daily in Anti-Retroviral-Naïve, Incarcerated Patients with HIV Infection Taking Directly Observed Treatment. CID. 2002; 34:511-518.
5. Mitty JA, Stone VE, Sands M, et al. Directly Observed Therapy for the Treatment of People with Human Immunodeficiency Infection: A Work in Progress. CID. 2002; 34:984-990.
6. Starrett S. Unpublished observations.